K030885

APR 1 8 2003

stryker INSTRUMENTS

4100 East Milham Avenue
Kalamazoo, MI 49001
Phone (616) 323-7700
(800) 253-6210

Device Name:

Trade Name:	Stryker PainPump2
Common Name:	Electromechanical Ambulatory Infusion Pump
Classification Name:	Pump, Infusion: 21 CFR 880.5725, Class II

Device Sponsor:

Manufacturer:	Stryker Instruments 4100 E. Milham Avenue Kalamazoo, MI 49001 Registration No.: 1811755

Regulatory Class: Class II

Summary of Safety and Effectiveness:

The Stryker PainPump2 is intended an electromechanical pump which delivers a controlled amount of medication to the patient for the purpose of managing pain. The pump delivers medication using one or both of the following drug delivery profiles: an hourly flow rate and a bolus PCA (patient controlled anesthetic) dosing option. Routes of administration may be intraoperative, subcutaneous or percutaneous. Dosage rates and patient lock out times are programmed into the PainPump2 unit by the physician.

The Stryker PainPump2 is contraindicated for infusion of blood and blood products, insulin, or life-supporting medication.

The Stryker PainPump2 2-Site Infusion Set is a kit that is comprised of a 2-Site infusion set, introducer needles, syringe, dressings and catheter securement accessories.

The Stryker PainPump2 is substantially equivalent in intended use, safety, and effectiveness to existing infusion pump systems being marketed by I-Flow Corporation.

The Stryker PainPump2 does not raise any new safety and efficacy concerns when compared to similar devices already legally marketed. Therefore, the Stryker PainPump2 is substantially equivalent to these existing devices.

By: Nicole Petty
Nicole Petty
Regulatory Analyst

Dated: 3·20·03

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 8 2003

Ms. Nicole Petty
Regulatory Analyst
Stryker Instruments
4100 E. Milham Avenue
Kalamazoo, Michigan 49001

Re: K030885
Trade/Device Name: Modification to Stryker PainPump 2
Regulation Number: 880.5725, 880.5120
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN, BSO
Dated: March 20, 2003
Received: March 21, 2003

Dear Ms. Petty:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: _____

Device Name: Stryker PainPump2

Indications For Use:

PainPump2 is an electromechanical pump which delivers a controlled amount of medication to the patient for the purpose of managing pain. The pump delivers medication using one or both of the following drug delivery profiles: an hourly flow rate and a bolus PCA (patient controlled anesthetic) dosing option. Routes of administration may be intraoperative, subcutaneous, or percutaneous. Dosage rates and patient lock out times are programmed into the PainPump II unit by the physician.

The PainPump II is contraindicated for infusion of blood and blood products, insulin, or life-supporting medication.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The- Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K030885